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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/601,723 | 06/23/2003 | David L. Canfield | A279-USA | 8759 |

24677 7590 02/15/2006

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EXAMINER

ALEXANDER, JOHN D

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,723

Applicant(s)

CANFIELD ET AL.

Examiner

John D. Alexander

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/23/03, 1/3/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 5, 10, and 11 recite the limitation "the microstimulator electronics" in line 1 of Claim 5, lines 1 and 2 of Claim 10, and line 1 of Claim 11. There is insufficient antecedent basis for this limitation in the claims. Claim 1 recites the phrase "microstimulator electronics" but the electronics are included only inferentially and not actively claimed as a component of the apparatus. Claim 8 recites the limitation "the medical device electronics" in line 3, which also lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schulman (Patent No. 4071032).

- Regarding **Claims 1-4 and 17**, Schulman discloses an elongated hollow tube formed of ferrite, said hollow tube defining an interior region thereof for housing corresponding microstimulator electronics (Col. 10, lines 7-62, especially 52-55; Col. 11, lines 5-21 & 55-57; Col. 12, lines 15-29); an electrically conductive wire coil wound around an outer surface of the hollow tube and adapted for electrical communication with the microstimulator electronics (Figs. 5 & 8, element 37; Col. 7, lines 34-60); and a protective ceramic sleeve encasing the hollow tube and coil to insulate them from contact with body fluids (Fig. 8, element 74; Col. 12, lines 35-65).
- Regarding **Claims 5-11**, examiner notes that these claims attempt to further define microstimulator electronics, which were never actively required in Claim 1, and are therefore only truly limiting to the extent that the hollow tube from Claim 1 must be inherently capable of housing the electronics as further defined. Regardless, regarding Claim 5, Schulman discloses integrated circuitry (Col. 12, lines 21-24). Regarding Claim 8, Schulman discloses a silicone matrix to fill voids of the hollow tube (Fig. 1, element 25; Col. 3, lines 58-68; Col. 12, lines 39-41). Regarding Claim 10, Schulman discloses a rechargeable battery and rectifier circuit, wherein currents generated in the coil are rectified and used to recharge the battery (Col. 3, lines 44-53). Regarding Claim 11, Schulman discloses RF transmission and receiver circuitry, wherein the coil serves as an antenna (Col. 11, lines 26-33).

Claim Rejections - 35 USC § 102 / 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 102(b) as anticipated by Schulman (Patent No. 4071032), hereafter refereed to as '032, or, in the alternative, under 35 U.S.C. 103(a) as obvious over '032 in view of Schulman et al. (Patent No. 6164284), hereafter referred to as '284. It seems that the epoxy fill matrix disclosed by '032 inherently includes the characteristics of a "getter" (Col. 4, lines 7-8). Alternatively, '284 discloses an implantable microstimulator that includes IC circuits wrapped by ferrite plates and a coil and also teaches the use of a getter (Fig. 1; Figs. 10A&B; Col. 4, lines 10-36; Col. 13, lines 40-47). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teaching by '284 to modify the microstimulator epoxy filler of '032 to include a getter. The motivation would have been to increase the hermeticity of the implanted stimulator by absorbing fluid introduced therein ('284, Col. 13, lines 43-47).

Claims 15 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by '032 or, in the alternative, under 35 U.S.C. 103(a) as obvious over '032 in view of Schulman et al. (Patent No. 5405367), hereafter referred to as '367. Patent '032 discloses the use of several coil turns (Col.

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7, lines 42-43), which seems to anticipate the lower end of Applicant's broad range of "about 10 to 600." Alternatively, '367 discloses an implantable microstimulator that includes IC circuits wrapped by ferrite plates and a coil, wherein it is taught to provide approximately 200 turns of the coil (Figs. 3 & 4, element 11; Col. 10, lines 22-30). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teaching by '367 to modify the microstimulator coil of '032 to include approximately 200 turns. The motivation would have been to provide the necessary inductance ('367, Col. 10, lines 24-25).

Claim Rejections - 35 USC § 103

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over '032 in view of Schaldach, Jr. (Patent No. 6245092). As related above, these claims attempt to further define microstimulator electronics, which were never actively required in Claim 1. Regardless, '032 does not explicitly disclose that the integrated circuits are interconnected by a flex circuit and folded in a face-to-face fashion. Schaldach, Jr. disclose integrated circuitry for use in implanted medical devices, wherein the circuitry is interconnected on a folded, flexible substrate (Fig. 3, elements 5-5.4 & 11; Col. 2, lines 17-24 & 54-64; Col. 3, lines 30-46). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Schaldach, Jr. to modify the integrated microstimulator circuitry of '032 to include integrated circuits that are interconnected by a flex circuit and folded in a face-to-face fashion. The motivation would have been to provide increased compactness and miniaturization as well as simplification in surgical implantation and improved patient tolerance (Schaldach, Jr., Col. 1, lines 30-37; Col. 2, lines 14-16).

Claims 12-14, 16, 18-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patent '032 in view of '367.

- Regarding **Claims 12-14 and 18-21**, Patent '032 does not explicitly disclose that the ferrite tube has an inner diameter of *about* 1.78mm, outer diameter of *about* 2.26mm, and axial length of *about* 3mm or that the ceramic sleeve has an outside diameter in the range of *about* 3.2 to 8.0mm. As related above in rejection of Claims 15 and 22, Patent '367 discloses an implantable microstimulator that includes IC circuits wrapped by ferrite plates and a coil (Figs. 3 & 4, element 11; Col. 10, lines 22-30). Patent '367 further discloses that the microstimulator should have a diameter of about 2mm and an axial length of about 10mm. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by '367 to modify the microstimulator of '032 to include tube and sleeve dimensions that allow for overall microstimulator dimensions on the order of 2mm x 10mm. The motivation would have been to provide a small size that allows for easy implantation through the lumen of a hypodermic needle ('367, Col. 3, lines 56-60).
- Regarding **Claims 16 and 23**, Patent '032 does not explicitly disclose that the coil wire is *about* 44 gauge. Patent '367 further discloses that the microstimulator's coil should be of *approximately* 51-gauge wire. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teaching by '367 to modify the microstimulator coil of '032 to include wire that is *approximately* 51 gauge, which examiner considers to be *about* 44 gauge. The motivation would have been to provide the necessary inductance ('367, Col. 10, lines 24-25) and to minimize any increase in the diametric dimension necessitated by the coil.

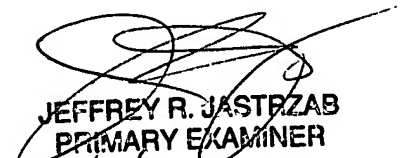
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Alexander whose telephone number is (571) 272-8756. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDA



JEFFREY R. JASTRZAB
PRIMARY EXAMINER
2/13/06